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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,230	01/20/2006	Philippe Erbs	REGIM 3.3-076	2237

530 7590 12/12/2007

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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	**PAPER NUMBER**
1633	

MAIL DATE	DELIVERY MODE
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,230	ERBS, PHILIPPE	
	Examiner	Art Unit	
	Maria Leavitt	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 35-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31, 35-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claims 1-11, 30, 31, 38 and 47, drawn to **a polypeptide** possessing Cytosine Deaminase (CDase) activity

II. Claims 12-29, 39, 40, 41, and 42-46 drawn **nucleic acid sequence** which encodes a polypeptide possessing CDase activity , a recombinant vector comprising said polynucleotide , a process for preparing a viral particle, a viral particle comprising said recombinant vector, a host cell comprising said nucleotide sequence and a composition comprising said nucleic acid sequence.

III. Claims 35-37, 48--52 are drawn to a method of **treating a disease** comprising administering a therapeutically effective amount of a nucleotide sequence.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

"If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present"

37 CFR 1.475 (d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)".

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking groups I-III appears to be that they all relate to a polypeptide having a uracil phosphoribosyl transferase (UPRTase) activity derived from a native UPRTase by mutation of one or several residues of said UPRTase, a nucleotide sequence coding for said UPRTase mutant, a vector for expressing said nucleotide sequence, a viral particle and a host cell as well as a composition containing polypeptide and method of treatment. However, prior art has taught the protein and gene or cDNA sequence of *C. kefyr* cytosine deaminase able to convert 5-fluorocytosine (5FC) to 5-fluorouracil (5FU) and use of the nucleic acid sequence in traditional suicide gene therapy methodologies (WO 2004/061079). Therefore, the technical feature linking the invention of groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

Inventions of **Group I drawn to a polypeptide** are structurally and functionally different from inventions of **Group II** drawn **to a recombinant vector derived** comprising a nucleic acid

sequence which encodes the polypeptide, because they are drawn to materially different compositions, having different chemical structures, physical properties and biological functions as the result of comprising either polypeptides or polynucleotides, which have different classifications and require separate searches; they are not obvious variants and deemed patentably distinct for the following reasons: polypeptides/proteins, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Moreover, because of the degeneracy of the genetic code, different nucleotide sequences can encode the same polypeptide sequence. Hence, the information provided by a polynucleotide of Group II can be used to make a materially different polypeptide than that of Group I. Moreover, inventions of **Group III drawn to** the method of **treating a disease in a subject** includes unique technical features that are not shared by the inventions of Groups I. For example, the invention of Group III requires administration of a test drug before that subject experience the disease e.g., cancer, which step is nor required by the polypeptide or nucleic acid of Groups I or II, respectively. Because these inventions are distinct for the reasons given above, and are separately classified and searched, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Species restriction

Should Groups **II** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

1) A genus of molecules as recited in claim 15 selected from one of the following molecules:

cationic lipids, cationic polymers, lysophospholipides and polypeptides.

The species are independent or distinct because there are **substances** having different chemical structures, physical properties, and biological functions. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

2) A genus of molecules as recited in claim 22 selected from one of the following molecules:

El, E2, E4 and LI-L5 regions of the adenoviral genome.

The species are independent or distinct because there are **deletions within the** adenoviral genome having different chemical structures, physical properties, and biological functions as the result of having different expressed genes. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

3) A genus of molecules as recited in claim 17 selected from one of the following molecules:

deletion I, II, III, IV, V and VI of the MVA genome

The species are independent or distinct because there are **deletions within the MVA genome** having different chemical structures, physical properties, and biological functions as the result of having different expressed genes. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

4) A genus of molecules as recited in claims 25 and 26 selected from one of the following molecules:

interleukins IL-2, IL-4,IL-7, IL-10 and IL-12, interferons, tumor necrosis factor (TNF), colony stimulating factors (CSF), IL-2 and INF γ

The species are independent or distinct because there are **molecules** having different chemical structures, physical properties, and biological functions as the result of having different expressed genes. Thus, the combined features of a particular species, distinct structurally and

functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

5) A genus of molecules as recited in claims 42 and 47 selected from one of the following molecules:

IL-2 and INF γ

The species are independent or distinct because there are **molecules** having different chemical structures, physical properties, and biological functions as the result of having different expressed genes. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

Should Groups **II or III** be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

6) A genus of vectors as recited in claim 14 selected from one of the following:

Plasmid and viral vectors.

The species are independent or distinct because there are **vectors** having different chemical structures, physical properties, and biological functions as the result of having different expressed genes. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

If applicant elect a viral vector, a further selection of species is required from the following vectors:

7) A genus of vectors as recited in claim 16 selected from one of the following: **a pox virus, from an adenovirus, from a retrovirus, from a herpes virus, from an alphavirus, from a foamyvirus or from an adenovirusassociated virus.**

The species are independent or distinct because there are **viruses** having different chemical structures, physical properties, and biological functions as the result of having different expressed genes. For example both an adenovirus and pox viruses are DNA viruses; however there are functionally different, for example, adenovirus vectors are advantageously used to efficiently infect most cell types, whereas pox virus can adventurously insert large sizes of DNA. Thus, the combined features of a particular species, distinct structurally and functionally, would not necessarily overlap with one another when a prior art search is conducted.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 12, and 35 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as

an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of

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